NEW YORK STATE DEPARTMENT OF HEALTH

GUIDELINES FOR DETERMINING BRAIN DEATH

DECEMBER 2005

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BACKGROUND

These guidelines represent a broad consensus. They incorporate the guidelines of the American Academy of Neurology (AAN) and add recommendations for brain death determination in children. These guidelines also draw upon a consensus-building process in New York State that included convening a Brain Death Guideline Panel in November 2004, and review of the guidelines by the New York State Task Force on Life & the Law in 2005.

PURPOSE

The purpose of these guidelines is to provide health care providers with information about New York State requirements for determining brain death, increase knowledge amongst health care practitioners about the clinical evaluation of brain death, and reduce the potential for variations in brain death determination policies and practices amongst facilities and practitioners within New York State. The Department of Health hopes that the issuance of these guidelines not only will help educate health care providers regarding such determinations, but also will increase the public's confidence that such determinations are made after a thorough and careful evaluation in accordance with accepted medical standards.

DEFINITION

Brain death is defined as the irreversible loss of all function of the brain, including the brainstem (see 10 N.Y.C.R.R. § 400.16). The three essential findings in brain death are coma, absence of brainstem reflexes, and apnea. An evaluation for brain death should be considered in patients who have suffered a massive, irreversible brain injury of identifiable cause. A patient determined to be brain dead is legally and clinically dead.

The diagnosis of brain death is primarily clinical. No other tests are required if the full clinical examination, including each of two assessments of brain stem reflexes and a single apnea test, are conclusively performed. In the absence of either complete clinical findings consistent with brain death, or confirmatory tests demonstrating brain death, brain death cannot be diagnosed.

Hospital Responsibilities Regarding Brain Death Determination

10 N.Y.C.R.R. § 400.16 requires all New York State hospitals to establish and implement written policies for determining brain death, including processes for:

- Privileging physicians to make brain death determinations in accordance with accepted medical standards;
- Notifying the next of kin or other person closest to the patient that brain death determination is in progress;
- Providing reasonable accommodation of an individual's religious or moral objection to use of the brain death standard to determine death; and
- Determining brain death via appropriate clinical examinations and tests in accordance with accepted medical standards.

Each of these responsibilities is addressed in further detail on the following pages.

Privileging

Each hospital should establish a process for identifying and privileging physicians to make brain death determinations. The application of the clinical criteria described in this policy requires the judgment of a physician competent in determining brain death. **Hospital policies may specify standards for training and assessing competency to determine brain death.** A physician need not be, or consult with, a neurologist or neurosurgeon in order to determine brain death.

The patient's attending physician should participate in the determination of brain death whenever possible. If the attending physician is not privileged by the hospital in the determination of brain death, another physician having such privileges must perform the assessment and make the final determination.

Notification

New York State law requires hospitals to make reasonable efforts to notify the next-of-kin or person closest to the individual that the process of evaluating brain death has begun. Staff notifying such persons should be prepared to respond to basic questions concerning the patient's condition and the process of determining brain death.

Reasonable Accommodation

Hospitals must establish written procedures for the reasonable accommodation of the individual's religious or moral objections to use of the brain death standard to determine death when such an objection has been expressed by the patient prior to the loss of decision-making capacity, or by the next of kin or other person closest to the individual. Policies may include

specific accommodations, such as the continuation of artificial respiration under certain circumstances, as well as guidance on limits to accommodation. Policies may also provide guidance on the use of other resources, such as clergy members, ethics committees, counselors and conflict mediators to address objections or concerns. Since objections to the brain death standard based solely upon psychological denial that death has occurred or on an alleged inadequacy of the brain death determination are not based upon the individual's moral or religious beliefs, "reasonable accommodation" is not required in such circumstances. However, hospital staff should demonstrate sensitivity to these concerns and consider using similar resources to help family members accept the determination and fact of death.

Brain Death Determination Policies

Hospitals are required to establish written policies that specify the process for determining brain death, including a description of examinations and tests to be employed, and who can perform the exam and make the determination. The following pages provide guidance to clinicians and facilities making such determinations. The Department recommends hospitals use these guidelines in developing their own written policies while tailoring confirmatory testing to the specific resources available in their facility.

Responsibilities of Physicians Determining Brain Death

The diagnosis of brain death is primarily clinical. No other tests are required if the full clinical examination, including each of two assessments of brain stem reflexes and a single apnea test, is conclusively performed. In the absence of either complete clinical findings consistent with brain death, or confirmatory tests demonstrating brain death, brain death cannot be diagnosed and certified. These guidelines apply to patients one year of age or older. *Please see Appendix for the determination of brain death in children less than 1 year old*. The steps for determining brain death are summarized below, and explained in more detail in the following pages:

- 1. Evaluate the irreversibility and potential causes of coma;
- 2. Initiate the hospital policy for notifying the next of kin;
- 3. Conduct and document the first clinical assessment of brain stem reflexes;
- 4. Observe the individual during a defined waiting period for any clinical inconsistencies with the diagnosis of brain death;
- 5. Conduct and document the second clinical assessment of brain stem reflexes;
- 6. Perform and document the apnea test;
- 7. Perform confirmatory testing, if indicated;
- 8. If the individual's religious or moral objection to the brain death standard is known, implement hospital policies for reasonable accommodation;
- 9. Certify brain death; and
- 10. Withdraw cardio-respiratory support in accordance with hospital policies, including those for organ donation.

Step 1: Evaluation of Coma

The determination of brain death requires the identification of the proximate cause and irreversibility of coma. Severe head injury, hypertensive intracerebral hemorrhage, aneurysmal subarachnoid hemorrhage, hypoxic-ischemic brain insults and fulminant hepatic failure are potential causes of irreversible loss of brain function. The physician should assess the extent and potential reversibility of any damage, and also rule out confounding factors such as drug intoxication, neuromuscular blockade, hypothermia, or other metabolic abnormalities that cause coma but are potentially reversible.

The evaluation of a potentially irreversible coma should include, as may be appropriate to the particular case:

- Clinical or neuro-imaging evidence of an acute CNS catastrophe that is compatible with the clinical diagnosis of brain death;
- Exclusion of complicating medical conditions that may confound clinical assessment (e.g., no severe electrolyte, acid-base, or endocrine disturbance);
- Lack of significant hypothermia or hypotension:
 - Core temperature:
 - (age ≥ 18 years) $\geq 32^{\circ}$ C (89.6°F)
 - (age \geq 1 year < 18 years) Consider age specific norms
 - (age < 1 year) See appendix
 - Systolic blood pressure:
 - $(age \ge 18 \text{ years}) \ge 90 \text{ mm Hg}$
 - (age \geq 1 year < 18 years) Consider age specific norms
 - (age < 1 year) See appendix
- Exclusion of drug intoxication or poisoning.

If intoxicants such as barbiturates are present, levels need not be zero, but should be in a range that would not normally be expected to interfere significantly with consciousness. Since it is impossible to stipulate specific levels for every drug, experienced clinical judgment is necessary. A cerebral blood flow study that demonstrates absent intracranial blood flow is consistent with the diagnosis of brain death even in the presence of CNS depressants. If neuromuscular junction blocking agents have been used, there should be evidence of neuromuscular transmission, i.e. deep tendon reflexes, other clinical muscle function, or responses to electrical stimulation of motor nerves, before beginning the determination of brain death.

Step 2: Notify Next of Kin

The facility must make diligent efforts to notify the person closest to the patient that the process for determining brain death is underway. Consent need not be obtained but requests for reasonable accommodation based on religious or moral objections should be noted and referred to appropriate hospital staff. Where family members object to invasive confirmatory tests, physicians should rely on the guidance of hospital counsel and the ethics committee.

Step 3: Initial Clinical Assessment of Brain Stem Reflexes

The brain death determination requires two clinical assessments of brain function, separated by a period of hours. The apnea test is typically performed after the second evaluation of brainstem reflexes.

The three essential findings in brain death are coma or unresponsiveness, absence of brainstem reflexes, and apnea. The determination of brain death verifies these findings by the following clinical indications:

- **Coma or unresponsiveness:** no cerebral motor response to pain in all extremities (nail-bed pressure) and supraorbital pressure
- Absence of brainstem reflexes
 - Pupils
 - No response to bright light
 - Size: midposition (4 mm) to dilated (9 mm)
 - Ocular movement
 - No oculocephalic reflex (testing only when no fracture or instability of the cervical spine or skull base is apparent)
 - No deviation of the eyes to irrigation in each ear with 50 ml of cold water (tympanic membranes intact; allow 1 minute after injection and at least 5 minutes between testing on each side)
 - Facial sensation and facial motor response
 - No corneal reflex
 - No jaw reflex (optional)
 - No grimacing to deep pressure on nail bed, supraorbital ridge, or temporomandibular joint
 - Pharyngeal and tracheal reflexes
 - No response after stimulation of the posterior pharynx
 - No cough response to tracheobronchial suctioning

<u>Confounding Factors</u>: The following conditions may interfere with the clinical diagnosis of brain death, so that the diagnosis cannot be made with certainty on clinical grounds alone. In such instances, confirmatory tests are recommended.

- Severe facial or cervical spine trauma
- Preexisting pupillary abnormalities
- Toxic levels of any sedative drugs, aminoglycosides, tricyclic antidepressants, anticholinergics, antiepileptic drugs, chemotherapeutic agents, or neuromuscular blocking agents
- Sleep apnea or severe pulmonary disease resulting in chronic retention of CO₂

<u>Clinical observations compatible with the diagnosis of brain death</u>: The following manifestations are occasionally seen and should not be misinterpreted as evidence for brainstem function:

- Spontaneous movements of limbs other than pathologic flexion or extension response
- Respiratory-like movements (shoulder elevation and adduction, back arching, intercostal expansion without significant tidal volumes)
- Sweating, flushing, tachycardia
- Normal blood pressure without pharmacologic support or sudden increases in blood pressure
- Absence of diabetes insipidus
- Deep tendon reflexes; superficial abdominal reflexes; triple flexion response
- Babinski reflex

Step 4: Interval Observation Period

After the first clinical exam, the patient should be observed for a defined period of time for clinical manifestations that are inconsistent with the diagnosis of brain death. Most experts agree that a 6 hour observation period is sufficient and reasonable in adults and children over the age of 1 year. Longer intervals are advisable in young children. *Please see appendix for the determination of brain death in children less than 1 year old.*

When a confirmatory test confirms the diagnosis of brain death, the interval between clinical assessments can be shortened to 2 hours. If any part of the clinical determination including the apnea test cannot be completed, one of the confirmatory tests is required and the interval may be shortened to 2 hours.

Step 5: Repeat Clinical Assessment of Brain Stem Reflexes

The exam as described in Step 3 above should be repeated in full and documented. When clinical circumstances prohibit completion of any steps in the clinical examination, these should be documented.

Step 6: Apnea Test

Generally, the apnea test is performed after the second examination of brainstem reflexes. The apnea test need only be performed once when its results are conclusive.

Before performing the apnea test, the physician must determine that the patient meets the following conditions:

- Core temperature \geq 36.5°C or 97.7°F
- Euvolemia. Option: positive fluid balance in the previous 6 hours
- Normal PCO_{2.} Option: arterial PCO₂ \ge 40 mm Hg
- Normal PO₂. *Option:* pre-oxygenation to arterial PO₂ \ge 200 mm Hg

After determining that the patient meets the prerequisites above, the physician should conduct the apnea test as follows:

- Connect a pulse oximeter and disconnect the ventilator.
- Deliver 100% O₂, 6 l/min, into the trachea. *Option:* place a cannula at the level of the carina.
- Look closely for respiratory movements (abdominal or chest excursions that produce adequate tidal volumes).
- Measure arterial PO₂, PCO₂, and pH after approximately 8 minutes and reconnect the ventilator.
- If respiratory movements are absent and arterial PCO₂ is ≥ 60 mm Hg (*option:* 20 mm Hg increase in PCO₂ over a baseline normal PCO₂), the apnea test result is positive (i.e. it supports the diagnosis of brain death).
- If respiratory movements are observed, the apnea test result is negative (i.e. it does not support the clinical diagnosis of brain death).
- Connect the ventilator if, during testing, the systolic blood pressure becomes < 90 mm Hg (or below age appropriate thresholds in children less than 18 years of age) or the pulse oximeter indicates significant oxygen desaturation, or cardiac arrhythmias develop; immediately draw an arterial blood sample and analyze arterial blood gas. If PCO₂ is \geq 60 mm Hg or PCO₂ increase is \geq 20 mm Hg over baseline normal PCO₂, the apnea test result is positive (it supports the clinical diagnosis of brain death); if PCO₂ is < 60 mm Hg and PCO₂ increase is < 20 mm Hg over baseline normal PCO₂, the result is indeterminate and a confirmatory test can be considered.

Step 7: Confirmatory Testing as Indicated

When the full clinical examination, including both assessments of brain stem reflexes and the apnea test, is conclusively performed, no additional testing is required to determine brain death. In some patients, skull or cervical injuries, cardiovascular instability, or other factors may make it impossible to complete parts of the assessment safely. In such circumstances, a confirmatory test verifying brain death is necessary. These tests may also be used to reassure family members and medical staff. Based on clinical indications, confirmatory testing may sometimes precede other aspects of the determination of brain death; it may also occur in the interval between assessments of brainstem reflexes or after.

Documentation should indicate which parts of the clinical examination could not be completed safely, along with the reason. Even when confirmatory testing is consistent with brain death, as when absent cerebral blood flow is documented, brain death protocols still require two assessments of brain stem reflexes. Any of the suggested tests may produce similar results in patients with catastrophic brain damage who do not (yet) fulfill the clinical criteria of brain death. The diagnosis of brain death rests on the clear determination of the cause of coma, the elimination of potentially confounding factors, the results of the clinical exams and those of confirmatory tests as indicated.

The choice of a confirmatory test is dictated in large part by practical considerations, i.e. availability, advantages and disadvantages. Currently available confirmatory tests are listed below, in alphabetical order, along with the findings consistent with brain death and complicating factors.

- Angiography (conventional, computerized tomographic, magnetic resonance, and radionuclide): Brain death confirmed by demonstrating the absence of intracerebral filling at the level of the carotid bifurcation or Circle of Willis. The external carotid circulation is patent, and filling of the superior sagittal sinus may be delayed.
 - Radionuclide angiography (CRAG) does not adequately image vasculature of the posterior fossa.
 - MRI angiography can be quite challenging in an ICU patient because of magnet incompatibility with lines, ventilator tubing and other hardware.
 - Cerebral arteriography: This test is often difficult to perform in a critically ill, unstable patient.
- Electroencephalography: Brain death confirmed by documenting the absence of electrical activity during at least 30 minutes of recording that adheres to the minimal technical criteria for EEG recording in suspected brain death as adopted by the American Electroencephalographic Society, including 16-channel EEG instruments. (See reference 1 below.)
 - The ICU setting may result in false readings due to electronic background noise creating innumerable artifacts.
- Nuclear brain scanning: Brain death confirmed by absence of uptake of isotope in brain parenchyma and/or vasculature, depending on isotope and technique used. ("hollow skull phenomenon"). (See reference 2 below.)
- Somatosensory evoked potentials: Brain death confirmed by bilateral absence of N20-P22 response with median nerve stimulation. The recordings should adhere to the minimal technical criteria for somatosensory evoked potential recording in suspected brain death as adopted by the American Electroencephalographic Society.
- Transcranial doppler ultrasonography: Brain death confirmed by small systolic peaks in early systole without diastolic flow, or reverberating flow, indicating very high vascular resistance associated with greatly increased intracranial pressure.
 - Since as many as 10% of patients may not have temporal insonation windows because of skull thickness, the initial absence of Doppler signals cannot be interpreted as consistent with brain death.

Step 8: Reasonable Accommodation

When an objection to brain death based on religious or moral grounds is raised, physicians should follow hospital policy for providing reasonable accommodation.

Step 9: Certification of Brain Death

Brain death can be certified by a single physician privileged to make brain death determinations. However, before a patient can become an organ donor, New York State law requires that the time of brain death must be certified by the physician who attends the donor at his death and one other physician, neither of whom shall participate in the process of transplantation. This requirement ensures that all evaluations meet accepted medical standards, and that all participants can have confidence that brain death determination has not been influenced by extraneous factors, including the needs of potential organ recipients.

When two physicians are required to certify the time of death, i.e., when organ donation is planned, both physicians should affirm that the clinical evaluation meets accepted medical standards, and that the data fully support the determination of brain death. Generally, both physicians should observe the patient, review the medical record, and note whether any additional information is required to make a definitive determination. Neither physician should certify brain death unless all aspects of the determination have been completed.

Medical Record Documentation: All phases of the determination of brain death should be documented in the medical record; a sample checklist and certification notice are appended at the end of this guidance. The medical record must indicate:

- Etiology and irreversibility of coma/unresponsiveness
- Absence of motor response to pain
- Absence of brainstem reflexes during two separate exams, separated by hours
- Absence of respiration with $PCO_2 \ge 60 \text{ mm Hg}$
- Justification for, and result of, confirmatory tests if used

Step 10: Withdraw cardio-respiratory support in accordance with hospital policies, including those for organ donation

When a patient is certified as brain dead and the ventilator is to be disconnected, the family should be treated with sensitivity and respect. If family members wish, they may be offered the opportunity to attend while the ventilator is disconnected. However, family members should be prepared for the possibly disturbing clinical activity that they may witness. When organ donation is contemplated, ventilatory support will conclude in the operating room and family attendance is not appropriate.

Appendix: Determination of Brain Death In Children Less Than One Year of Age

1. General Policy Statement.

The brains of infants and young children have increased resistance to damage and may recover substantial functions even after exhibiting unresponsiveness on neurological examination for longer periods as compared to adults. When applying neurological criteria to determine death in children younger than one year, longer observation periods are required.

2. The patient must not be significantly hypothermic or hypotensive for age.

3. Observation Periods According to Age.

The recommended observation period depends on the age of the patient and the laboratory tests utilized. Ages listed assume the child was born at full term. Between the ages of 2 months and 1 year, an interval of at least 24 hours should be used. Between the ages of 7 days and 2 months, the minimum interval should be 48 hours.

- Reliable criteria have not been established for the determination of brain death in children less than 7 days old.
- Seven days to two months: Two examinations and electroencephalograms (EEGs) should be separated by at least 48 hours.
- Two months to one year: Two examinations and EEGs should be separated by at least 24 hours. A repeat examination and EEG are not necessary if a concomitant radionuclide (CRAG) or other angiographic study demonstrates no visualization of cerebral arteries.

References for Voluntary Consensus Guidelines for Determining Brain Death:

1. American Electroencephalographic Society. Guideline three: minimum technical standards for EEG recording in suspected cerebral death. J Clin Neurophysiol. 1994 Jan; 11(1): 10-13.

2. Donohue KJ, Frey KA, Gerbaudo VH, Nagel JS, Shulkin B. Society of Nuclear Medicine Procedure Guideline for Brain Death Scintigraphy. J Nucl Med. 2003 May; 44(5): 846-51.

3. Quality Standards Subcommittee of the American Academy of Neurology. Practice parameters for determining brain death in adults (summary statement). Neurology. 1995 May; 45(5): 1012-4.

4. Task Force for the determination of brain death in children. Guidelines for the determination of brain death in children. Neurology 1987; 37: 1077-1078.

5. Wijdicks EF. Determining brain death in adults. Neurology. 1995 May; 45(5): 1003-11.

6. Wijdicks EF. The diagnosis of brain death. N Engl J Med. 2001 Apr 19; 344(16): 1215-21.

Brain Death Checklist

Patient's Name:

	Examination #1	Examination #2
THE CAUSE OF BRAIN DEATH IS		
KNOWN AND IRREVERSIBLE Exclusion of complicating medical conditions that may confound the clinical assessment of brain death.	Date & Time: Physician Initials: Yes No Explanation:	Date & Time: Physician Initials: Yes No Explanation:
Is core body temperature ≥ 32° C (89.6°F)?	Date & Time: Initials: Yes No Explanation:	Date & Time: Initials: Yes No Explanation:
If CNS depressants or neuromuscular blockade present, are concentrations sufficiently low that they will not interfere with the assessment for brain death?	Date & Time: Initials: Ves No Explanation:	Date & Time: Initials: Ves No Explanation:
Is systolic blood pressure ≥ 90mm Hg ?	Date & Time: Initials: Ves No Explanation:	Date & Time: Initials: Ves No Explanation:
In children <18 years of age, are core body temperature and systolic blood pressure in an acceptable range for age?	Date & Time: Initials: Yes No Explanation:	Date & Time: Initials: Yes No Explanation:
The relevant family member or appropriate party has been notified of the intention to initiate the determination of brain death.	Date & Time: Initials: Yes No Explanation:	Date & Time: Initials: Ves No Explanation:

DETERMINATION OF UNRESPONSIVENESS		
Absence of supraspinal motor response to pain in all extremities (nail bed pressure and supraorbital pressure)	Date & Time: Initials: Yes No Explanation:	Date & Time: Initials: Yes No Explanation:
ABSENCE OF BRAINSTEM		
REFLEXES No pupillary response to light	Date & Time:	Date & Time:
Size: midposition (4mm) to dilated (9mm)	Initials: Yes No Explanation:	Initials: Yes No Explanation:
No oculocephalic reflex (Note: to be tested only when fracture or instability of the cervical spine and skull base have been excluded.)	Date & Time: Initials: Yes No Explanation:	Date & Time: Initials: Yes No Explanation:
No deviation of the eyes to irrigation of each ear with 50 ml of cold water. (Note: the tympanic membrane must be intact.)	Date & Time: Initials: Yes No Explanation:	Date & Time: Initials: Yes No Explanation:
No corneal reflex	Date & Time: Initials: Yes No Explanation:	Date & Time: Initials: Yes No Explanation:
No jaw reflex (optional)	Date & Time: Initials: Yes No Explanation:	Date & Time: Initials: Yes No Explanation:

No response to stimulation of the posterior pharynx and/or no cough response to tracheobronchial suctioning.	Date & Time: Initials: Yes No Explanation:	Date & Time: Initials: Ves No Explanation:
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Apnea Testing Prerequisites:		
Core temperature $\geq 36.5^{\circ}$ C or 97.7°F	Yes	
Euvolemia. Option : positive fluid balance in the previous 6 hours	Yes	
Normal PCO ₂ . Option: arterial PCO ₂ \geq 40 mm Hg	Yes	
Normal PO ₂ Option: pre-oxygenation to obtain arterial PO ₂ \geq 200mm Hg if possible.	Yes	
Apnea Testing Process:		
Deliver 100% oxygen via the ventilator for 10 minutes prior to starting the test.	Complete	
Draw a baseline arterial blood gas.	Complete	
Connect a pulse oximeter and disconnect the ventilator		
Deliver 100% oxygen into the trachea via cannula in the ET tube, at 6 l/minute.	Complete	
If tolerated, leave the patient off the ventilator for 8-10 minutes.	Complete	
Observe the patient carefully for respiratory movements.	Complete	
Draw another blood gas at the end of the 8-10 minutes and reconnect the ventilator.	Complete	
Apnea Testing Documentation:		
Length of apnea test		
PCO ₂ at end of test		
Did patient breath during the test? Ves No Comments:		

Yes		No	Comments:
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If the PCO₂ \geq 60mm Hg or the PCO₂ increase was at least 20 mm Hg over the initial normal baseline PCO2, the test is positive and supports the diagnosis of brain death. **Confirms Brain Death**

If the patient does not tolerate the apnea test, as evidenced by significant drops in blood pressure and/or oxygen saturation, or the development of significant arrhythmias, the test is uninterpretable and either should be repeated, or supplanted with a confirmatory test. If the pCO2 does not exceed 60 mmHg after 10 minutes of apnea, or does not increase 20 mm from normal baseline, the test does not confirm the diagnosis of brain death. **Does Not**

Confirm Brain Death

If Confirmatory Testing Is Performed	
Which test was performed?	
What was the interpretation of the test?	

Documentation of Brain Death

A physician shall certify a patient as brain dead when the patient fulfills the criteria described in these guidelines. Before a patient can be an organ donor, a second physician certification is required.

Physician Certification:	
Print Name	Date/Time of death
Signature	
Second Physician Certification (Necessary for org	gan donation):
Print Name	_ Date/Time of death:
Signature	

New York State Department of Health Brain Death Guidelines Review Panel <u>Participants</u>

Tia Powell, MD (Chair) Executive Director New York State Task Force on Life and the Law

Elaine Berg, MPA President and CEO New York Organ Donor Network

Gregory Castiglia, MD Neurosurgeon Buffalo Neurosurgery Group

Julius Cheng, MD, MPH Medical Director, Burn-Trauma ICU University of Rochester Medical Center

Joseph Jack Fins, MD, FACP Chief, Division of Medical Ethics Cornell University

John Halperin, MD Professor of Neurology, NYU School of Medicine Attending Neurologist, North Shore University Hospital

Jeffrey Oppenheim, MD Neurosurgeon Hudson Valley Neurosurgical Associates

Margaret Paroski, MD Interim Vice President of Health Affairs University of Buffalo Wouter J. Rietsema, MD Vice President of Medical Affairs CVPH Medical Center

Stanley Rothman, MD Associate Professor of Pediatric Neurology Mount Sinai School of Medicine

Maryann Sharpe-Casesse, BSN, MSN, CPTC Chair, Ethical Practice & Human Rights Council New York State Nurses Association

Mark Simon Chief Executive Officer Upstate New York Transplant Services, Inc.

Raymond Walsh, MD Pediatric Intensive Care Specialist Albany Medical Center

James Zisfein, MD Chief of Neurology Lincoln Medical & Mental Health Center

Judy Doesschate, JD Division of Legal Affairs

Lisa McMurdo, RN Division of Healthcare Standards and Surveillance